IUCLID

Data Set

New Chemical: Substance ID: 68610-51-5

CAS No.: 68610-51-5

EINECS Name: Phenol 4-methyl-, reaction products with dicyclopentadiene

and isobutylene

EINECS No.: 271-867-2

CAS Name: Phenol, 4-methyl-, reaction products with

dicyclopentadiene and isobutylene

Molecular Formula: C10H12.C7H8O.C4H8

Type: Lead organization

Name: American Chemistry Council (formerly Chemical Manufacturers

Association) Rubber and Plastics Additives (RAPA) HPV Panel

Street: 1300 Wilson Boulevard Town: 22209 Arlington, VA Country: United States

Country: United States
Phone: 703-741-5600
Telefax: 703-741-6091

Type: cooperating company Name: Bayer Corporation Country: United States

Type: cooperating company

Name: Ciba Specialty Chemicals Corporation

Country: United States

Type: cooperating company Name: Crompton Corporation

Country: United States

Type: cooperating company Name: Flexsys America L.P.

Country: United States

Type: cooperating company

Name: Noveon, Inc (formerly BF Goodrich)

Country: United States

1. General Information

Type: cooperating company

R.T. Vanderbilt Company, Inc. Name:

Country: United States

cooperating company Type:

The Goodyear Tire & Rubber Company Name:

United States Country:

Type: cooperating company

Eliokem Inc. Name: Country: United States

Type: cooperating company The Lubrizol Corporation Name:

United States Country:

Type: cooperating company

Name: Alco Chemical Corporation

Country: United States

Number of Pages: 33

Chapter (profile): Chapter: 1, 2, 3, 4, 5, 7

Reliability (profile): Reliability: without reliability, 1, 2, 3, 4

Flags (profile): Flags: without flag, confidential

1.1 General Substance Information

Substance type: organic Physical status: solid

Purity: > 98 % w/w

Result: Molecular weight: 650

05-APR-98

1.1.1 Spectra

1.2 Synonyms

4-Methylphenol reaction products with dicyclopentadiene and isobutylene

Butylated reaction product of p-cresol and dicyclopentadiene

p-Cresol, dicyclopentadiene, isobutylene reaction products

Polymeric hindered phenol

SANTOWHITE ML

VULKANOX SKF

WINGSTAY L

WINGSTAY L HLS

WINGSTAY L-HLS

WINGSTAY LA

WTR Number 69

1.3 Impurities

1.4 Additives

2.1 Melting Point

Value: 118.3 degree C

Method: OECD Guide-line 102 "Melting Point/Melting Range"

Year: GLP: yes

WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with Test Substance:

dicyclopentadiene and isobutylene)

Reliability: (1) valid without restriction

(32)

Value: 115 degree C

Method: other: ASTM D-1519

Year: 1991 GLP: no data

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Reliability: (2) valid with restrictions

Although this study was probably not conducted to GLP, the

test parameters used were based on a known and well

established procedure.

(21)

2.2 Boiling Point

Value:

Method: other: Not relevant

2.3 Density

Type:

1.0736 g/cm3 at 20 degree C Value:

OECD Guide-line 109 "Density of Liquids and Solids" Method:

Year: 1997 GLP: yes

Test Substance: WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

(1) valid without restriction Reliability:

(32)

Type:

Value:

other: ASTM D-891 Method:

Year: 1991 GLP: no data

Remark: Specific Gravity is 1.10

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Reliability: (2) valid with restrictions

Although this study was probably not conducted to GLP, the

test parameters used were based on a known and well

established procedure.

(21)

2.3.1 Granulometry

Type of

distribution:

Method: other: Not relevant

2.4 Vapour Pressure

< .00000032 hPa at 25 degree C Value:

Method: Directive 84/449/EEC, A.4 "Vapour pressure"

Year: 1997 GLP: yes

Test Substance: WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with

Dicyclopentadiene and isobutylene)

Result: Actual value was < 3.2x10-5 Pa

Reliability: (1) valid without restriction

(30)

2.5 Partition Coefficient

log Pow: 7.17 - 8.17 at 30 degree C

Method: OECD Guide-line 117 "Partition Coefficient (n-octanol/water),

HPLC Method"

Year: 2000 GLP: yes

Test Substance: WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: The partition coefficient was estimated by the HPLC method

using isocratic elution. The procedure conformed to those outlined in EC Directive 92/69/Annex V method A8 and OECD Guidelines 117 (1995). The HLPC system used: Detector-Jasco UV-875 set to 220 nm; Column-Spherisorb 5 um ODSB, 25x0.46 cm; Mobile phase-Acetonitrile/water, 90/10; Column temperature-30 degrees C. The dead time TO was measured using formamide as a non-retained solute (void volume marker). The HPLC column was calibrated for partition coefficient against retention time using calibration substances of known partition ceefficients dissolved in appropriate mobile phase. Duplicate estimations were performed for each series. The capacity factor, K, was calculated from the retention times using the following equation, where TR is retention time for the calibration substance: K= (TR-TO)/TO. The log of the capacity factor is plotted against the log of the partition coefficient to derive a calibration graph. The test substance was dissolved in mobile phase and the retention time recorded. The estimated partition coefficient was calculated from the calibration

graph obtained using the calibration substances.

Result: The partition coefficient for the major components of WINGSTAY

L-HLS (Phenol 4-methyl-, reaction products with

dicyclopentadiene

7.17 to 8.17 with a 95% confidence limit in the range

5.86 to 13.10.

Reliability: (1) valid without restriction

(28)

> 10 at 25 degree C log Pow:

Method: other (measured): Official Journal of the European

Communities, L383 A-Part A.8

Year: 1995 GLP: no

Test Substance: WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with

Dicyclopentadiene and isobutylene)

Result: The Pow of WINGSTAY L-HLS at 25 degrees C was concluded to be

greater than 10000.

Reliability: (2) valid with restrictions

> Although the study was not conducted to GLP, the test parameters were based on a scientifically sound procedure and the study was

properly conducted.

(26)

2.6.1 Water Solubility

Value: < .2 other: ug/ml at 20 degree C

Method: Directive 84/449/EEC, A.6 "Water solubility"

Year: 1997 GT.P: yes

WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with Test Substance:

Dicyclopentadiene and isobutylene)

Reliability: (1) valid without restriction

(31)

2.6.2 Surface Tension

Method: other: Not relevant

2.7 Flash Point

Value: Type:

Method: other: Not relevant

Year:

2.8 Auto Flammability

Value:

Method: other: Not relevant

2.9 Flammability

Result: non flammable

Method: Directive 84/449/EEC, A.10 "Flammability (solids)"

Year: GLP: yes

Test Substance: WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with

Dicyclopentadiene and isobutylene)

(1) valid without restriction Reliability:

(32)

2.10 Explosive Properties

Result:

Method: other: Not relevant

2.11 Oxidizing Properties

Result:

Method: other: Not relevant

2.12 Additional Remarks

Not relevant Memo:

3.1.1 Photodegradation

Type:

Method: other: Not relevant

3.1.2 Stability in Water

Type:

Method: other: the test substance is essentially insoluble in water.

See Water Solubility 2.6.1

Year: GLP:

Test substance:

3.1.3 Stability in Soil

3.2 Monitoring Data (Environment)

3.3.1 Transport between Environmental Compartments

3.3.2 Distribution

3.4 Mode of Degradation in Actual Use

Memo: Not relevant

3.5 Biodegradation

Type: Inoculum:

other: Under conditions of study, not inherently biodegradable Result:

other: OECD Guide-line 301B and OECD Guide-line 302B Method:

1998 Year: GLP:

Test Substance: WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with

Dicyclopentadiene and isobutylene)

Reliability: (1) valid without restriction

(29)

Date: March 2003 3. Environmental Fate and Pathways Substance ID: 68610-51-5

3.6 BOD5, COD or BOD5/COD Ratio

BOD5 Method: other

Year:

GLP: no

BOD5: 2200 mgO2/1

COD

Method: other

Year: GLP: no

COD: .92 mg/g substance

Remark: The COD was on the water soluble portion

TOC was 33.4 mg/l on the preparation and 9.5 mg/l on the same

preparation after filtration on cellulose acatate (0.2

WINGSTAY L (Phenol 4-methyl-, reaction products with Test Substance:

dicyclopentadiene and isobutylene)

Reliability: (2) valid with restrictions

Although this study was probably not conducted to GLP, the

test parameters used were based on a known and well

established procedure.

(19)

3.7 Bioaccumulation

3.8 Additional Remarks

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

Type: semistatic

Species: Oncorhynchus mykiss (Fish, fresh water)

Exposure period: 96 hour(s)

Unit: mg/l Analytical monitoring: yes

NOEC: .2 LC50: > .2

Method: OECD Guide-line 204 "Fish, Prolonged Toxicity Test: 14-day

Study"

Year: 1998 GLP: yes

Test Substance: WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: Prior to the test initation, a 20 mg/mL stock solution was

prepared by adding the test substance directly to methanol. The solution was further diluted with methanol to prepare a 2 $\,$ mg/mL stock solution. The 2 $\,$ mg/mL stock solution was added to dilution water to provide a nominal concentration of 0.2 $\,$ mg/L.

The identical procedure was used to prepare fresh test

solutions at 24 hour intervals. Throughout the test, all test

media were clear, colorless solutions.

The toxicity test was conducted in 15 Liter aquaria, each of which contained 14 L of test solution. One test aquarium was maintained for the treatment level (0.2 mg/L, the solubility limit of the test substance in water) and for the two

controls, one containing methanol (0.01%) at the same concentration as the test medium and one containing dilution

water only.

The 96-hour semistatic limit toxicity test was carried out with renewal of the test media at 24 hour intervals. The test vessels were covered with perspex lids during the study. Seven (7) Oncorhynchus mykiss (trout) (mean for fork length of 5.6 cm and mean weight of 1.894 grams) were placed in each of the test vessels at the start of the study. The fish were not fed

during the study. The vessels were aerated during the study. Remark:

The solubility limit of the test substance was 0.2 mg/L in

water

Result: Samples of the freshly prepared stock solution were analysed

for the test substance after preparation. No analysis of the

0.2 mg/L test medium was possible. The mean measured concentrations of the test substance in 20 and 2 mg/mL methanol stock solutions were 18.524 and 2.021 mg/mL $\,$

(representing 93 and 101% of nominal cocentrations). There were no mortalities in any fish exposed to the test substance throughout the duration of the study. The 24-, 48-, 72- and 96-hours LC50 values of the test substance to $\underline{\text{Oncorhynchus}}$ $\underline{\text{mykiss}}$ (Trout) were observed to be > 0.2 mg/L (the highest nominal concentration tested). The highest concentration

causing no mortality was 0.2 mg/L.

Reliability: (1) valid without restriction

(25)

4.2 Acute Toxicity to Aquatic Invertebrates

Species: Daphnia magna (Crustacea)

Exposure period: 48 hour(s)

Unit: mg/1 Analytical monitoring: no

NOEC: .2 EC50: > .2

Method: OECD Guide-line 202, part 1 "Daphnia sp., Acute

Immobilisation Test"

Year: 1998

GLP: yes

Test Substance: WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: The toxicity test was conducted in 150 mL glass crystallizing

dishes, each of which contained 100 mL of the exposure solution. Four replicate test vessels were established for each treatment level and the dilution water and methanol controls. A stock solution was prepared by direct addition of

the test substance to methanol to provide a nominal

concentration of 20 mg/mL then further diluted with methanol to prepare a stock solution of 2.0 mg/mL. The 2 mg/mL stock solution was added to dilution water to provide a nominal concentration of 0.2 mg/L. Two control treatments were prepared, one containing methanol (0.01%) at the same

concentration as the test medium and one containing dilution water only. An identical procedure was used to prepare fresh

test media after 24 hours.

The 48-hour limit semistatic toxicity test was carried out with renewal of the test medium after 24 hours. Aliquots of 100 mL of the test medium were added to four replicate test vessels at a nominal exposure concentration of 0.2 mg/L. The 0.2 mg/L test medium was clear and colorless at the start and

end of each exposure period.

Remark: The solubility limit of the test substance was 0.2 mg/L in

water

Result: The combined limit and range-finding test resulted in no

immobility to the $\underline{\text{Daphnia}}$ $\underline{\text{magna}}$ exposed to the 0.2 mg/L (the solubility limit of the test substance in water) treatment

level for 48 hours.

Reliability: (1) valid without restriction

(24)

4.3 Toxicity to Aquatic Plants e.g. Algae

Species: Selenastrum capricornutum (Algae)

Unit: mg/l Analytical monitoring: yes

NOEC: .2 **EC50:** > .2

Method: OECD Guide-line 201 "Algae, Growth Inhibition Test"

Year: 1998

GLP: yes

Test Substance: WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method:

Prior to test initiation, a 20 mg/mL stock solution was prepared by adding the test substance directly to methanol, then it was further diluted with methanol to prepare a stock solution of 2 mg/mL. The 2.0 mg/mL stock solution was added to nutrient medium to provide a nominal concentration of 0.2 mg/L (the solubility limit of the test substance in water). The treatment level for this study was 0.2 mg/L. Two control treatments were prepared, one containing methanol (0.01%) at the same concentration as the test medium and one containing growth medium only.

The test vessels were 250-mL Erlenmeyer glass flasks. Test substance treatment aliquots (100 mL), prepared as described above, were added to five (5) Erlenmeyer flasks. Eight (8) flasks were prepared containing the methanol control medium and four (4) flasks were prepared containing the growth medium only. Two (2) of the four (4) growth medium control flasks, three (3) of the five (5) test substance flasks and six (6) of the eight (8) methanol control flasks were inoculated with sufficient Selenastrum capricornutum to achive a nominal cell concentration of 10,000 cells/mL. The remaining flasks were used for determining water quality and background electronic count.

The flasks were loosely capped and incubated in a cooled orbital incubator under constant illumination.

Remark:

The solubility limit of the test substance was 0.2 mg/L in water

Result:

Samples of freshly prepared stock solutions were analyzed after preparation, no analysis of the 0.2 mg/L test medium was possible. The mean measured concentrations of the test substance in 20 and 2 mg/L methanol stock solutions were 18.552 and 1.882 mg/L (representing 93 and 94 % of nominal concentrations).

The pH of the test media increased by more than 1.5 units in some of the control and test vessels. Growth of the control cultures was greater than a factor of 16 over the 72-hours test period, demonstrating that the environmental conditions were acceptable for the study. The growth rate of the algae exposed to the test substance was comparable to the algae exposed to the negative controls. Based on the areas under the growth curves and the average specific growth rate, the 0- to

72-hours EC50 were observed to be > 0.2 mg/L, the highest concentration tested. The highest NOEC of the test substance was established to be 0.2 mg/L for this study.

Reliability: (1) valid without restriction

(27)

4.4 Toxicity to Microorganisms e.g. Bacteria

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

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4.5.2 Chronic Toxicity to Aquatic Invertebrates

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TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms

4.6.2 Toxicity to Terrestrial Plants

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4.6.3 Toxicity to other Non-Mamm. Terrestrial Species

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4.7 Biological Effects Monitoring

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4.8 Biotransformation and Kinetics

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4.9 Additional Remarks

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50 Species: rat

Sex:
Number of
 Animals:
Vehicle:

Value: > 16000 mg/kg bw

Method: other

Year: 1964 **GLP:** no

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Remark: Animals fed single doses exhibited no clinical signs of

toxicity during a two week observation period

Reliability: (4) not assignable

Data from original report were not available. However, data

(result) may be useful for information purposes.

(5)

Type: LD50 Species: rat

Sex: male/female

Number of

Animals: 10

Vehicle: other: corn oil
Value: > 200 mg/kg bw

Method: other: United States Department of Transportation Regulations,

49CFR173.132(1992)

Year: 1993 **GLP:** yes

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Reliability: (1) valid without restriction

(16)

Type: LD50 Species: rat

Sex: male/female

Number of

Animals: 10 (5 males and 5 females)

Vehicle:

Value: > 5010 mg/kg bw
Method: other: No data

Year: 1986 GLP: yes

Test substance: SANTOWHITE ML (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Methods: The test article in corn oil was administered in a single oral

dose of 5,010 mg/kg.

Results: No animals died during the 14-day observation period. No signs of

toxicity were reported in the males. Lethargy during the first day was observed in the females. No abnormalities were observed

at the terminal necropsy.

Reliability: (1) valid without restriction

(12)

Type: LD50 Species: rat

Sex: male/female

Number of

Animals: 10

Vehicle: other: corn oil
Value: > 5000 mg/kg bw

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: A group of ten Spraque-Dawley rats (5 males and 5 females)

were administered the test substance via gavage (corn oil) in a single oral dose at 5000 mg/kg. Clinical observations were recorded at 1 and 4 hours post dose (+ or - 15 minutes) and daily thereafter through day 15. Body weights were recorded on Day 1 (fasted), Day 8 and Day 15. At study termination,

the animals were subjected to a gross necropsy.

Result: All animals survived the 15 day testing/observation period.

Soft feces and/or poor grooming were observed in some animals on Day 1 through 3. No other clinical signs were observed. All animals exhibited increases in bodyweight throughout the study. Mottled kidneys were observed in one male at terminal necropsy. No other vivible lesions were observed in any other

animals at necropsy.

Reliability: (1) valid without restriction

(2)

5.1.2 Acute Inhalation Toxicity

Type: LC50
Species: rat

Sex: Number of

Animals: 10

Vehicle:

Exposure time: 1 hour(s)
Value: > 165 mg/1

Method: other: United States CFR Title 16, Federal Hazardous Labeling

Act, Part 1500.4 (1975)

Year: 1975 **GLP:** no

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: 10 male albino rats, initially weighing between 214 and 239

grams were exposed under dynamic conditions in a 38-liter glass inhalation chamber for one hour to an approximate 200 mg/liter concentration of the test material. Exposure to the

test substance was accomplished through the use of a

pulse-puff generator through which a constant airflow of 10 liters per minute was passed into the chamber. Total airflow

through the chamber was 10 liters/minute. The nominal concentration was determined from the ratio of the total $% \left(1\right) =\left(1\right) +\left(1\right) +\left($

quantity (mg) of the test material aerosolized in one hour to the total airflow (liters) through the chamber during that

hour. The animals were observed for pharmacotoxic

manifestations and mortality during the exposure and during

the 14-day post exposure observation period.

Remark: Exposure for one-hour to a nominal concentration of 165 mg of

the test substance/liter of air ($18.4\ \%$ percent under the desired 200 mg/liter) was not lethal to rats. At the end of

the 14 day observation period, no animals had died.

Result: At the beginning of the exposure, all rats were hyperactive

and several rats were preening and appeared to be coughing or sneezing. This condition was followed by nasal discharge in several rats. After 35 minutes of exposure, the fur of all the rats was covered with the test substance. After 40 minutes, the rats could not be observed due to the density of the aerosol achieved. Upon removal from the exposure chamber, all rats exhibited a slight nasal discharge and their fur was saturated with the test substance. No deaths occured. On Day 1 post exposure, all rats were hyperactive and exhibited a red nasal discharge. On Day 2 post exposure, several rats

exhibited a red crusty exudate and hair loss around the eyes and nose. At the end of the 14-day observation period, several rats still exhibited a slight red exudate and hair

loss around the eyes and nose. No animals died.

Reliability: (2) valid with restrictions

Although the study was old and was not conducted to GLP, the test parameters were based on an established procedure for that time

period and was conducted by a well known laboratory.

(6)

5.1.3 Acute Dermal Toxicity

Type: LD50
Species: rabbit
Sex: male/female

Number of

Animals: 4 (2 males and 2 females)

Vehicle:

Value: > 5010 mg/kg bw
Method: other: No data

Year: 1986 GLP: yes

Test substance: SANTOWHITE ML (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: Test article in deionized water at a dose of 5,010 mg/kg to the

skin of New Zealand albino rabbits for 24 hours. The animals were observed for 14 days. No signs of toxicity were observed during the study and no visceral abnormalities observed at necropsy.

Reliability: (1) valid without restriction

(11)

5.1.4 Acute Toxicity, other Routes

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species: rabbit
Concentration: .5 grams

Exposure: Occlusive

Exposure Time: 24 hour(s)

Number of

Animals: 6

PDII:

Method: other: United States Federal Hazardous Substances Act,

16CFR1500.41 (1974)

Year: 1974 **GLP:** no

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: A single 24-hour dermal application of 0.5 grams of the test

substance was applied to clipped and premoistened intact and abraded skin sites on the back of six (6) New Zealand White rabbits. The areas were covered with one-inch square gause patches. The rabbits were immobilized in restrainers and their trunks were wrapped in nonabsorbent binders for the 24-hour exposure period. Observations were made at 24 and 72 hours.

Remark: Did not produce primary skin irritation in a standard assay

conducted with New Zealand White rabbits. The primary irritation score was 0.25.

Reliability: (2) valid with restrictions

Although the study was old and was not conducted to GLP, the test parameters were based on an established procedure for that time $\frac{1}{2}$

period and was conducted by a well known laboratory.

(9)

Species: rabbit
Dose: 0.5 grams

Exposure: Occlusive
Exposure Time: 4 and 24 hours

Number of

Animals: 12

Method: other: United States EPA

Year: 1986 GLP: yes

Test substance: SANTOWHITE ML (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Methods: 0.5 gm of test article applied to intact skin to two groups of

six rabbits. One group was exposed to the test article for 4 hours and the other for 6 hours. No skin irritation was observed.

Reliability: (1) valid without restriction

(14)

Species: rabbit

Dose: 500 other: mg/site

Exposure: Occlusive

Exposure Time: 4 hour(s)

Number of

Animals: 6

PDII:

Year: 2000 GLP: yes

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: The test substance (at 500 mg/site) was applied to each of

three sites on the clipped dorsal trunk of six (6) New Zealand White rabbits (3 male and 3 female). The upper dorsal sites were exposed to the test article for 3- and 60-minutes. The

exposure period for the mid dorsal site was 4-hours.

Observations for dermal irritation were recorded immediately after patch removal and daily throuh Day 15 for the 3-minute and 60-minute exposure sites. The 3-minute site was also scored at 60-minutes after patch removal. Observations of the 4-hour exposure sites were recorded immediately , 24, 48 and 72 hours after patch removal and daily thereafter. Grading of

irritation was according to the Draize method.

Result: Rabbit sites in the 3-minute exposure group showed no erythema

and no edema. Rabbit sites in the 60-minute exposure group showed very slight erythema and no edema. Rabbit sites in the 4-hour exposure group showed very slight erythema and no edema. The Primary Irritation Index (4-hour exposure) was

calculated to be 0.2.

Reliability: (1) valid without restriction

(15)

5.2.2 Eye Irritation

Species: rabbit Concentration: 40 mg

Dose:

Exposure Time: 24 hour(s)

Comment: Number of

Animals: 6

Result: slightly irritating
EC classificat.: not irritating

Method: other: United States EPA

Year: 1986 GLP: yes

Test substance: SANTOWHITE ML (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Methods: 0.1 gm applied for 24 hours to 6 New Zealand albino rabbits.

Score: 1.3/110

Reliability: (1) valid without restriction

(13)

5.3 Sensitization

Type: Guinea pig maximization test

Species: Guinea pig

Concentration: Induction 5 % active intracutaneous

substance

Induction 25 % active occlusive epicutaneous

substance

Challenge 5 % active occlusive epicutaneous

substance

Number of

Animals: 36

Vehicle:

Result: sensitizing Classification: sensitizing

Method: OECD Guide-line 406 "Skin Sensitization"
Year: 2000 GLP: yes

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: For the intradermal induction phase of the study, the vehicle

control and test article groups (10 animals/sex/group) and a positive control group (3 animals/sex) were administered intradermal injections (0.1 ml each) at three (3) clipped sites between the shoulders of each guinea pig. One week

later, the injection sites were reclipped.

For the topical induction phase, the test sites were occluded with 25 % of the test substance for 48-hours. The vehicle control and positive control groups were topically induced in the same manner with 100% petrolatum or 0.1% 1-chloro-2,4,-

dinotrobenzene (DNCB) in petrolatum, respectively.

Two weeks after the topical induction, all test article and vehicle control animals were dermally challenged with occluded patches of 5% test substance in petrolatum on the left flank and 100 % petrolatum on the right flank. After 24-hours, the sites were unwrapped and cleaned. Challenged sites were graded for skin reactions at 24- and 48-hours after unwrapping. Positive control animals were challenged in the same manner with 0.01% DNCB in petrolatum on the left flank and 0.05% DNCB on the right flank.

Based upon the results of the primary challenge, the animals in the test article groups were rechallenged six (6) days later with the test substance at 5% (w/v).

Result: The test substance demonstrated a potential to produce mild

dermal sensitization when administered to Hartley Guinea pigs.

Based on the observations made in the study, the test

substance intradermally induced at 5% and topically induced at 25 % did elicit a mild sensitization response (Grade II) when challenged and rechallenged at 5% of the test substance.

Reliability: (1) valid without restriction

(18)

5.4 Repeated Dose Toxicity

Species: rat Sex: male/female

Strain: other: Cr/CD BR Rat

Route of admin.: oral feed Exposure period: 28 day

Frequency of

treatment: daily

Post. obs. period:

Doses: 0, 1000, 5000, 10000, 25000, or 50000 ppm in the diet

Control Group: yes, concurrent no treatment

NOAEL: 1000 ppm LOAEL: 5000 ppm Method: other

Year: 1989 **GLP:** yes

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Results: In the 25000 and 50000 ppm groups treatment was discontinued due

to severe systemic toxicity after 10 days of exposure. During the first week of test materials admistration 1/5 males and 0/5 females died at 25000 ppm and 2/5 males and 1/5 females died at 50000 ppm. Observations included decreased body weight and food consupmtion. Internal hemorrhaging was observed at necropsy. No animals in the 1000 and 5000 ppm groups died. In the 10000 ppm group one male and one female died during the treatment period. Internal hemorrhage was observed in these animals. Higher prothrombin and activated partial thromboplastin times were

observed in a dose-related manner in males at 5000 and 10000 ppm. Mean liver weights and liver weight relative to final body weights

were significantly higher in the 5000 and 10000 ppm group females compared to those of the controls. No microscopic evaluation of tissues was done in this dose-range finding study. Based on the data from this study, dietary levels of 500, 1500 and

4500 ppm were selected for evaluation in a definitive

90-day dietary study.

Reliability: (2) valid with restrictions

This study was not intended to be a guideline study. It was designed to be a dose-range finding study for the 90-day feeding

study and gave useful data for dose selection.

(22)

Species: rat

Sex: male/female

Strain: other: CrL/CD BR Rat

Route of admin.: oral feed Exposure period: 90 days

Frequency of

treatment: daily

Post. obs. period:

Doses: 0, 500, 1500, or 4500 ppm in diet

Control Group: yes, concurrent no treatment

NOAEL: 500 ppm **LOAEL:** 1500 ppm

Method: OECD Guide-line 408 "Subchronic Oral Toxicity - Rodent:

90-day Study"

Year: 1989 GLP: yes

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: Test material was added to the diets of 15 male and 15 female

rats at 0, 500, 1500 or 4500 ppm test material for 90 days.

Animals were observed for signs of toxicity. Body weight and food

consumption were measured. Clinical pathology parameters,

ophthalmology and organ weights were determined at the termination of the study. Macroscopic examination of all animals was done at necropsy. Kidneys, liver, lungs, and gonads from all animals were examined microscopically. In addition, selected tissues from the

control and high dose group were also examined.

Result: No test chemical effects on body weights, food consumption or

clinical observations were seen. Statistically significant

increases in prothormbin times and activated partial

thromboplastin times were observed in high dose males. No effects on clinical chemistry parameters were observed except for higher cholesterol in high dose females. No eye changes were seen. Liver weights were statistically significantly increased in the high dose groups without evidence of microscopic changes. Liver weights in the in mid-dose groups were also increased, but the increase was not statistically significant. Female adrenal weights were slightly increased at the mid-dose and statistically significantly increased at the high dose. Microscopic evaluation of tissues

showed no treatment related changes.

Reliability: (1) valid without restriction

(23)

5.5 Genetic Toxicity 'in Vitro'

Type: Salmonella typhimurium/Escherichia coli mutation assay

System of

testing: Salmonella typhimurium strains TA 98, TA100, TA1535, TA1537 and

Escherichia coli strain WP2uvrA

Concentration: 100, 250, 500, 750, and 1000 micrograms/plate

Metabolic

activation: with and without

Result: negative

Method:

Year: 1995

GLP: yes

Test Substance: WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: The test article was dissolved in DMSO. Vehicle and postive

controls were included in the assays.

Positive controls were 2-nitrofluorene (TA98 and TA1538 without metabolic activation); sodium azide (TA100 and TA1535 without metabolic activation); 9-aminoacridine (TA1537 without metabolic activation); methyl methanesulfonate (WP2uvrA without metabolic activation); and 2-Aminoanthracene (TA98, TA100, TA1535, TA1537,

TA 1538, and WP2uvrA with metabolic activation).

The assay used the plate incorporation methodology. Following incubation, revertant colonies (mutations) were counted. The exogenous metabolic activation system was derived Aroclor-induced rat liver (S9). The plates were incubated for 68 hours at 37 degrees C. Vehicle and positive controls were included in the assay. All doses of the test article, the vehicle control, and positive controls were plated in triplicate.

Based on the range finding test, the doses for the mutation assay were selected at 100, 250, 500, 750 and 1000 μ plate with and without S-9 activation

The results of the initial assay were confirmed in an independent test using the preincubation method of exposure.

Remark: Range finding test was conducted with TA100 and WP2uvrA

at doses of 5, 10, 50, 100, 500, 1000 and 5000 ug/plate with and without rat liver S-9 metabolic activation. Toxicity was observed at 1000 ug/plate without metabolic activation (RCE = 78%). With metabolic activiation, toxicity was observed at all doeses(RCE = 66% to 80%). Heavy percipitate at 5000 ug/plate precluded

evaluation of the test plates. Percipitates were oberved at 1000

ug/plate.

In the initial and confirmatory assays, all strains treated with the test article showed a mean reversion frequency that was similar to the corresponding solvent control, and there was no evidence of

a dose-response relationship.

Result: The test substance was considered negative for inducing

reverse mutations with and without metabolic activation.

Reliability: (1) valid without restriction

Type: Ames test/Salmonella Plate Incorporation Assay

System of

testing: Salmonella typhimurium TA-98, 100, 1535, 1537, and 1538

Concentration: 50, 167, 500, 1670, and 5000 ug/plate

Metabolic

activation: with and without

Result: negative

Method:

Year: 1986 GLP: yes

Test substance: SANTOWHITE ML (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: Study was done according to OECD Guidelines for Testing Chemicals

(1981) and EPA Health Affect Guidelines (1982).

The test article was dissolved in ethanol. Solvent and positive

controls were included in the assay.

Positive controls were 2-nitrofluorene (TA98 and TA1538 without metabolic activation); sodium azide (TA100 and TA1537 without metabolic activation); 9-aminoacridine (TA1535 without metabolic activation); and 2-anthramine for all strains with metabolic

activation.

The assay used plate incorporation methodology. Following incubation, revertant colonies (mutations) were counted. The exogenous metabolic activation system was derived from Aroclor 1254 induced male Sprague-Dawley rat liver (S9). The plates were incubated for 48 hours at 37 degrees C. All doses of the test article, the vehicle control, and positive controls were plated in

triplicate.

A range-finding test was conducted with TA100 and TA1538. The test article was evaluated at doses from 50.0 to 5000 ug/plate. The plates were evaluated for growth of the background lawn and

frequency of spontaneous revertants.

Remark: In the range-finding test toxicity was observed at 5000 ug/plate.

The test article percipitated at this dose.

All strains treated with the test article showed a mean reversion frequency that was similar to the corresponding solvent control.

Result: The test substance was considered negative for inducing reverse

mutations with and without metabolic activation.

Reliability: (1) valid without restriction

(10)

Type: Cytogenetic assay

System of

testing: Chromosomal Aberrations Assay in Chinese Hamster Ovary (CHO) Cells

Concentration: Without metabolic activiation:

50.0, 100, 225, 300 ug/mL (20-hr harvest

With metabolic activation:

100, 250, 500, 750, 1000 ug/mL (10-hr and 20-hr harvests)

Metabolic

activation: With and without S-9 from Sprauge-Dawley rat liver induced with

Aroclor 1254

Result: negative

Year: 1991

GLP: yes

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: The test article was dissolved in DMSO and all assays included

negative and solvent controls.

Mitomycin C was used as the positive control without activation

and cyclophosphamide with metabolic activation.

Range-finding assays were conducted with and without metabolic activation. Doses of 0.0333ug/ml to 1010 ug/ml in half-log series were tested. CHO cells were cultured for approximately 23 hours. Cells were harvested, fixed and evaluated for toxicity and mitotic

index.

Based on the results of the range-finding assays, 10-hr and 20-hr harvest times were selected for the chromosome abberation assay. Without metabolic activation CHO cells were incubated with 5-bromo 2'-deoxyuridine (BrdUrd) for the selected exposure times. With metabolic activation the cells were incubated with the S-9 for two hours, washed and cultured were incubated with BrdUrd for the selected exposure times. Coldemid was added two hours before harvest. Cells were harvested, fixed, and stained. One hundred cells per each replicate culture at each dose level and controls were evaluated for chromosome damage. An independent confirmatory assay was conducted at the same doses and exposure times.

Remark:

In the range-finding assay without metabolic activiation, total cellular toxicity was observed in the culture dosed with 1010 ug/ml. Severe cell cycle delay was evident in the cultures dosed with 101 and 337 ug/ml. Significant reduction in the mitotic index were observed in cultures dosed with 99.7, 332 and 997 ug/ml. No cell cycle delays or significant reductions in mitotic index were evident in cultures with metabolic activation. With metabolic activation, slight toxicity was observed at 1010 Ug/mL.

No cell cycle delay was observed.

No statistically significant increases in chromosome aberrations were observed without or with metabolic activation in the initial

or confirmatory assay.

Result: The test substance was considered negative for inducing

chromosomal aberrations in Chinese hamster ovary cells with and

(8)

without S-9 metaboic activation.

Reliability: (1) valid without restriction

Type: DNA damage and repair assay

System of

testing: E. coli Pol A+ and Pol A1- Assay

Concentration: 10, 100, 320, 1000 ug/plate (without metabolic activation)

10, 100, and 1000 ug/plate (with metabolic activation)

Metabolic

activation: with and without

Result: negative

Method:

Year: 1980 **GLP:** no

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: The DNA Damage Study in E. coli was conducted following The

Goodyear Tire & Rubber Company's, Health, Safety and

Government Compliance Test Method 79-11.

Cultures of Escherichia coli strains W3110 (pol A+) and p3478 (pol A1-) were cultured overnight and diluted to a practical density of approximately 2000 cells/ml. Replicate 100 uL aliquots of these diluted cultures were distributed into separate sterile tubes. Each tube then received 10 uL of diluted test chemical or solvent. For metabolic activation assays, 50 uL aliquots of S-9 microsomal preparation were added to each applicable tube. The suspensions were incubated for one hour (activation assays) and two hours (non-activation assays) at 37 degrees C. Results were expressed as the Survival Index which is the % of Pol A1- survivors/plate as compared to its negative control divided by the % of Pol A+

survivors/plate as compared to its negative control.

Result: The test substance was negative in the E coli. Pol A1- Assay

for DNA damage.

Reliability: (2) valid with restrictions

Although was not conducted to GLP, the test parameters were based on a scientifically sound procedure and the study was properly $\frac{1}{2}$

conducted.

(20)

Type: Forward Mutation Assay - HGPRT locus in Chinese Hamster Ovary

Cells (CHO)

System of

testing: CHO-K1-BH4 Chinese hamster ovary (CHO) cells Concentration: 100, 200, 400, 600, 800, and 1000 ug/mL

Metabolic

activation: with and without

Result: negative Method: other

Year: 1991 GLP: yes

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: The test article was dissolved in DMSO and all assays included

negative and solvent controls.

5-Bromo-2'-deoxyuridine was used as the positive control without activation and 3-methylcholanthrene with metabolic activation.

Range-finding cytotoxicity test was conducted with and without metabolic activation to determine doses for the mutation assay. Doses from 1.95 to 1000 ug/mL were tested.

The CHO cells were exposed to the test article for four hours at 37 degrees C. The cells were grown in media containing 6-thioguanine (TG) for seven day. At the end of the expression period the cells were washed and allowed to grow for 7 to 10 days. Then, the colonies were fixed, stained and counted to determine the number of TG-resistant colonies. The procedure was identical with and without metabolic activiation.

An independent confirmation assay was conducted at the same doses as the intial assay.

Remark:

Preliminary cytotoxicity testing showed relative cell growth at 1000~ug/mL to be 80.1% of controls and with metabolic activation, relative cell growth was 22.8%.

In the mutation assays, the test article was moderately toxic without activation at the higher dose levels and weakly toxicity with activation at all dose levels. No increase in mutation frequecy was observed in cells treated with the test article.

Result:

The substance was considered negative for inducing forward mutations at the HGPRT locus in CHO cells under both nonactivation and activation conditions.

Reliability:

(1) valid without restriction

(7)

5.6 Genetic Toxicity 'in Vivo'

5.7 Carcinogenicity

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5.8 Toxicity to Reproduction

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5.9 Developmental Toxicity/Teratogenicity

Type: Developmental toxicity

Species: rat
Sex: female

Strain: Sprague-Dawley

Route of admin.: gavage

Exposure period: Days 6 to 19 of gestation

Frequency of

treatment: Daily
Duration of test: 20 days

Doses: 0, 1000, 2000 or 3000 mg/kg/day

Control Group: yes, concurrent vehicle

NOAEL Maternal

toxicity: 1000 mg/kg bw/day

NOAEL

Developmental: The benchmark dose (BMD) at the ED05 was estimated to be 740

mg/kg/day for the common fetal variations.

Method: OECD Guide-line 414 "Teratogenicity"

Year: 1998 **GLP:** yes

Test Substance: WINGSTAY L-HLS (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: Timed-pregnant CD (Spraque-Dawley) rats were exposed to the

test substance dissolved in corn oil and administered by oral gavage, once daily, on gestational days 6 through 19 at doses of 0, 1000, 2000, or 3000 mg/kg/day. The dosing volume was 10 ml/kg. There were 25 sperm-positive females per each group. Clinical observations were taken daily, except during the dosing period when they were made at least twice daily. At scheduled sacrifice on gestation day 20, the dams were evaluated for body, liver and gravid uterine weights. Ovarian corpora lutea were counted and fetuses were dissected from the uterus, counted, weighed, sexed and examined for external abnormalities. Approximately one half of

the live fetuses in each litter were examined for visceral

malformations and variations. These fetuses were decapitated and the heads fixed in Bouin's solution. Intact fetuses were examined

for skeletal malformations and variations.

Remark: All fetal malformation and variation findings in this study

were those commonly observed in historical control CD rat fetuses in the performing laboratory and in published control

databases.

Pregnancy rates were high and equivalent across all groups. Four (4) females were not pregnant. No dams died, aborted or delivered early. One (1) female was removed from the study due to intubation (dosing) errors. All pregnant animals had one (1) or more live

fetuses at sacrifice.

Maternal body weights were equivalent across all groups for all time points examined. Maternal weight gain was statistically significantly lower (p< 0.05) in the 3000 mg/kg/day group for gestational days 6-9. Maternal absolute and relative liver weights were statistically significantly increased (p<0.01; Dunnett's

Test)at all doses. There were no specific treatment-related

clinical signs. Maternal feed consumption was reduced in the 3000 mg/kg/day group for gestational days 6-9 and significantly increased for gestational days 18-20. There were no treatment-related effects on any gestational parameters.

There were no treatment-related statistically or biologically significant changes in the incidence of pooled external, visceral, skeletal or total fetal malformations in this study. Percent fetuses with variations per litter was significantly increased at all doses, when sexes were combined, due to treatment-related increases in the incidence of two (2) common fetal skeletal variations; rudimentary rib on lumbar 1 (bilateral, right or left) and reduced ossification in the thoracic centra (normal cartilage, bipartite ossification center and dumbbell cartilage, bipartite ossification center). The number of fetuses (and litters) with skeletal variations were 34 (18) at 0 mg/kg/day, 65 (20) at 1000 mg/kg/day, 72 (22) at 2000 mg/kg/day and 94 (25) at 3000 mg/kg/day. The consequences, if any, of these findings are not known, especially in the absence of any effects on the fetal body weight, an usually very sensitive indicator of developmental toxicity.

Results:

The test substance administered by gavage during major organogenesis in CD (Spraque-Dawlwy) rats resulted in no indication of teratogenicity, but did result in increased incidences of common fetal skeletal variations at all dose levels without any other indicators of developmental toxicity. The NOAEL for maternal toxicity was 1000 mg/kg/day. Since a NOAEL for developmental toxicity was not established, a Benchmark dose (BMD) was determined (See Benchmark Dose (BMD) for "Developmental Toxicity"). The BMD at the ED05 was estimated to be 740 mg/kg/day for the common fetal variations.

Reliability: (1) valid without restriction (4)

Type: Benchmark Dose (BMD) for "Developmental Toxicity"

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: Reference Study: "Developmental Toxicity Evaluation with WINGSTAY L Administered by Gavage to CD (Sprague-Dawley) Rats", Research Triangle Institute Study Number

65C-6503-600/300/700 (Final Report April 13, 1998).

The developmental study concluded that WINGSTAY L was not teratogenic, but that there was a test article related increase in the incidence of common fetal skeletal variations. A NOAEL for this observation was not established experimentally. The purpose of this project was to estimate the NOAEL for this fetal effect using benchmark dose modeling.

The dose-response modeling was performed using U.S. EPA Benchmark Dose (BMD) software (Version 1.2). The Nested Logistic Dose-Response Model was used to calculate the BMD. The model estimated the Benchmark Response (BMR) at the 5%

effect level (ED05) and its lower confidence limit (LED05).

Result: The BMD at the ED05 was determined to be 740 mg/kg/day for

common fetal variations. The 95% lower confidence limit for

the ED05 was 530 mg/kg/day.

Reliability: (1) valid without restriction

(3)

5.10 Other Relevant Information

Type: other: Absorption, Distribution and Excretion

Test Substance: WINGSTAY L (Phenol 4-methyl-, reaction products with

dicyclopentadiene and isobutylene)

Method: OECD Guide-line 417

The study was designed following OECD Guidelines for Testing of Chemicals: No. 417, April 1984 and ECETOC, Technical Report No. 46, May 1992. This study was conducted in compliance with Good Laboratory Practices (GLP) following OECD and Swiss Guidelines. The effective average doses administered were 29.3 mg/kg for the males and 29.9 mg/kg for the females. The specific radioactivity and the concentration of the administration (LSC) to be 3.87 uCi/mg (0.14 MBq/mg) and 3.01 mg/ml, respectively. Prior to administering the dose by gavage, the rats were fasted overnight. Four males and 4 female BRL-HAN, Wister rats that were 6-8 weeks old were used for the study. Levels of radioactivity in urine and feces were followed for 168 hours after a single oral administration. Additionally, at sacrifice (168 hours after administration) the residual radioactivity in the blood, plasma and organs/tissues (gastro-intestional tract, liver, kidney, adrenal gland, epididymes, ovaries, eyes, bone, brain, lung, muscle, spleen, thyroid gland, other tissues/organs and carcass) was determined.

 ${\tt Remark:}$

The majority of the WINGSTAY L was not absorbed and passes through the gastrointestinal tract. Within 48 hours of dosing, approximately 90% of the dose was excreted in the feces.

Very small amounts were absorbed and excreted in the urine. Excreted in the urine was 0.1% to 0.2% of the administered dose over the seven (7) day period.

The low level of additional excretion in the feces 48 hours after dosing suggests that part of the absorbed dose may be excreted in the bile.

Small percentage is retained in the body seven (7) days after a single dose. Only 1.5% to 2.4% of the radioactivity remained in the tissue, As expected, the highest concentration (ug-eq WINGSTAY L/g of tissue) of the radiolabeled material was in the fat.

Result: Total mean radioactivity recovered was males: 94.02 +/-

1.14% and females: 96.34 + /- 3.42%.

The total amount of radioactivity recovered in feces at 168 hours was 91.90 +/- 1.41% of the radioactivity administered in the males and 93.32 +/- 3.31% in the females. The majority was accounted for within 48 hours (males: 90.05 +/- 1.21%, females: 90.43 +/- 2.35%), indicating the test article was poorly absorbed.

Excretion via urine was very low, in total amounting to only 0.1 + / - 0.07% in the males and 0.20 + / - 0.12% in the females. Radioactivity was mainly excreted within the first 48 hours after administration, representing on average 0.0 + / - 0.07% of the radioactivity administered in the males and 0.16 + / - 0.11% in the females.

The total excreted radioactivity (total from feces, urine and cage waste) amounted to 92.50 +/- 0.79% in the males and to 93.94 +/- 3.2% in the females.

14C-WINGSTAY L was rapidly eliminated from the body. During the first 48 hours an average of 90% of the administered dose was excreted via the feces. An additional 1.9 to 2.9% was excreted in feces over the next 5 days. 0.1 to 0.2 % of the administered dose was excreted via urine over 7 days while 1.5 to 2.4% was recovered in rat tissues at end of 7 days.

Reliability: (1) valid without restriction

(1)

5.11 Experience with Human Exposure

Date: March 2003

6. References Substance ID: 68610-51-5

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